

**UNITED STATES DISTRICT COURT**  
**DISTRICT OF MASSACHUSETTS**

**IN RE: FRESENIUS  
GRANUFLO/NATURALYTE  
DIALYSATE PRODUCTS LIABILITY LITIGATION MDL NO.: 1:13-MD-2428**

**FILED UNDER SEAL  
ORDER GRANTING LEAVE TO FILE ENTERED OCTOBER 12, 2017**

This Document Relates to:

Mervin Boyd, Individually and as Wrongful  
Death Beneficiary of Judith Boyd,  
Cause No. 1:13-cv-11717

Daniel Carter, Individually and as Wrongful  
Death Beneficiary of Anniece Carter,  
Cause No. 1:13-cv-12459

Joyce Marie Clark, Individually and as Wrongful  
Death Beneficiary of Edward Lee Jenkins,  
Cause No. 1:13-cv-12460

Kathy Dennis, Individually and as Wrongful  
Death Beneficiary of Ruth Ann Dennis,  
Cause No. 1:13-cv-12467

Gloria Cothorn Dunaway, Individually and as Wrongful  
Death Beneficiary of Betty Sue Cothorn,  
Cause No. 1:13-cv-11714

Janice McGhee, Individually and as Wrongful  
Death Beneficiary of Henry McGhee,  
Cause No. 1:13-cv-13172

Michael McNulty, Individually and as Wrongful  
Death Beneficiary of Willie Enette McNulty,  
Cause No. 1:13-cv-12403

Kimberly Ross, Individually and as Wrongful  
Death Beneficiary of Stella Ross,  
Cause No. 1:13-cv-12478

Sophia Walker, Individually and as Wrongful  
Death Beneficiary of Hattie Myles,  
Cause No. 1:13-cv-12487

**REDACTED**  
**RESPONSE IN OPPOSITION TO MOTION FOR SUMMARY JUDGMENT ON THE**  
**CLAIMS OF OPT-OUT CASES INVOLVING NON-ARRHYTHMIA EVENTS OR**  
**INJURIES NOT PROXIMATE IN TIME TO THE LAST DIALYSIS**

**NOW INTO COURT**, through undersigned counsel, come the above-referenced Plaintiffs, who file their Response in Opposition to Motion for Summary Judgment on the Claims of Opt-Out Cases Involving Non-Arrhythmia Events or Injuries Not Proximate in Time to the Last Dialysis, and would show unto the Court the following:

There are genuine issues of material fact regarding the events that caused Plaintiffs' Decedent's deaths and proximity of those injuries to the last dialysis, and questions of fact are properly the province of a jury. The motion for summary judgment should be denied.

#### **STANDARD FOR SUMMARY JUDGMENT**

The standard for summary judgment is well-known. Summary judgment is appropriate only if there are no genuine issues of material fact and movant is entitled to judgment as a matter of law. Fed. R. Civ. Pro. 56. *Cross v. Cummins Engine Co.*, 993 F.2d 112 (5<sup>th</sup> Cir. 1993). Disputes over facts that might legitimately affect the outcome are material and, in applying the test, the court must view the evidence in the light most favorable to the nonmovant. *Anderson v. Liberty Lobby*, 477 U.S. 242 (1986).

#### **BURDEN OF PROOF**

At this stage in the litigation, to prove general causation Plaintiffs must proffer evidence that the product at issue is **capable** of causing their alleged injuries. *In Re Norplant Contraceptive Prods. Liab. Litig.*, 215 F.Supp. 2d 795, 830 (E.D. Tex. 2002)(emphasis added); *In Re Mirena IUD Prods. Liab. Litig.*, 202 F.Supp. 3d 304, 310 (S.D.N.Y. 2016). Generally, Plaintiff must then also proffer evidence that the product did, in fact, cause the injury in each individual case - i.e., specific causation. *Id.* However, in this litigation the only case-specific discovery that has occurred is contained in Plaintiff Fact Sheets, Defendant Fact Sheets and Lone

Pine Submissions.

## **ARGUMENT**

### **A. General Causation Cannot Be Credibly Contested**

The Fresenius Defendants cannot credibly contest general causation in this litigation. Attached hereto as Exhibit 1 is Plaintiffs' Omnibus Memorandum in Support of General Causation, which is incorporated by reference as if fully stated herein. Also attached as Exhibit 2 is the Memorandum of Decision and Order on the Plaintiffs' and Fresenius' Motions Pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.* and *Commonwealth v. Lanigan*, which was adopted by this Honorable Court in response to challenges to certain general causation and specific causation experts.

### **B. The Fundamental Flaw in Defendants' Argument in Support of Summary Judgment: The Hakim Memo**

In this their fourth separate motion for summary judgment, Defendants are yet again asking this Court to grant summary judgment relying on conclusions (in the Hakim Memo) that the Defendants themselves have argued are unreliable, unsupported and speculative. During the course of this litigation, the Fresenius Defendants successfully sought to have the Hakim Memo excluded as evidence of general causation. Fresenius argued that the Memo was unreliable, unsupported, and speculative. Now they are asking this Court to accept that the Hakim Memo should serve to justify summary judgment in their favor. During the course of the *Ogburn* litigation<sup>1</sup>, as Defendants are undoubtedly aware, the Plaintiff specifically agreed that she would not use the Hakim memo as evidence of causation.<sup>2</sup> In *Ogburn*, the Plaintiff asked the Court to

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<sup>1</sup>*Ogburn* was a bellweather trial in Commonwealth of Massachusetts Superior Court, Civil Action No. 2013-05050.

<sup>2</sup>See Plaintiff's Motion to Admit the November 4, 2011 Memorandum Into Evidence At Trial, attached hereto as Exhibit 3. ("If the Court so rules, Plaintiff will not use statements made

allow admission of the Memo only as to the issue of notice and as a non-hearsay party-admission.<sup>3</sup>

The Plaintiffs' theory of general causation is that excessive bicarbonate "total buffer"<sup>4</sup> (defined as the sum of bicarbonate a patient may be exposed to during dialysis) in the "dialysate" (specifically Fresenius' GranuFlo and NaturaLyte), is capable of causing metabolic alkalosis, arrhythmia, sudden cardiac arrest (SCA), and death. Plaintiffs have proffered expert testimony regarding the types of injuries that can be caused by GranuFlo and NaturaLyte and have proffered expert opinions regarding the length of time a patient may experience the elevated serum bicarbonate levels that could result in these injuries.

Plaintiffs, by and through discovery conducted thus far in this MDL, have proffered medical experts in nephrology, cardiology, epidemiology, biostatistics, and fluid dynamics to address the general causation question. These experts have opined that excessive bicarbonate total buffer in dialysates, including GranuFlo and NaturaLyte, causes a series of severe adverse health outcomes, including metabolic alkalosis, arrhythmia, sudden cardiac arrest (SCA), and death.<sup>5</sup> Plaintiffs' experts provide detailed, well-reasoned, well-supported generally acceptable mainstream text book opinions based on accepted and reliable methodologies. Plaintiffs experts have relied upon vast amounts of data and material, and not simply the Hakim Memo, as Defendants seem to argue.

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in the *Memo* to prove causation.")

<sup>3</sup> The Omnibus Memorandum of Decision and Order on Major Motions in Limine is attached hereto as Exhibit 4.

<sup>4</sup>Fresenius has used the term "total buffer" in countless documents.

<sup>5</sup>See Exhibit 1.

In fact, Plaintiffs' expert Dr. Steven Borkan survived a previous *Daubert* challenge on the very issue of the length of time in which patients may experience elevated serum bicarb levels after dialysis. The Court conducted a preliminary assessment of whether the reasoning or methodology underlying his testimony is scientifically valid, and of whether that reasoning or methodology could properly be applied to the facts in issue. The Court held that Dr. Steven Borkan could offer expert opinion testimony regarding the length of time a patient could experience elevated serum bicarb levels after dialysis, which increased levels could result in injury.

Additionally, the remaining opt-out Plaintiffs have provided Lone Pine expert reports which conclude, to a reasonable degree of medical certainty, that GranuFlo and NaturaLyte did in fact cause alkalosis, arrhythmia, sudden cardiac arrest, and death in these particular cases and in the relevant timeframe. All of the aforementioned create genuine issues of material fact which preclude summary judgment.<sup>6</sup>

**C. Plaintiffs Have Proffered Evidence That Serum Bicarbonate Levels May Remain Elevated For Up To 48 Hours After Dialysis and, in a Summary Judgment Context, Factual Disputes are Viewed in the Light Most Favorable to the Non-Movant**

Plaintiffs have proffered expert opinion testimony that establishes a longer post-dialysis risk window than the two hours suggested by Fresenius Defendants in their motion.

Dr. Steven Borkan is a nephrologist whom the Plaintiffs have named as an expert in general causation. Dr. Borkan has expressed the following opinions, in his expert report, at deposition, and at trial:

- Dr. Borkan referenced the "Graham Study" from 2001, involving [REDACTED]

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<sup>6</sup>See Expert Reports of Lucius Lampton, M.D., filed of record in each individual cause number, attached collectively as Exhibit 5.

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]” Fresenius has previously sought to preclude Dr. Borkan from expressing these opinions, but the motion was DENIED.<sup>7</sup>

- [REDACTED]  
[REDACTED]  
[REDACTED] Fresenius sought to preclude Dr. Borkan from expressing this opinion but the motion to preclude was DENIED<sup>8</sup>.
- [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED] Dr. Borkan Deposition at 51-53.
- Throughout his expert report, Dr. Borkan references various journal articles as support for his opinion that [REDACTED]  
[REDACTED]’ Dr. Borkan Report at 22.
- This Court has previously ruled that Dr. Borkan may testify that the greater amount of acetate, the great the potential impact on a patient’s serum bicarbonate.
- In his report, Dr. Borkan opined that “[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED].”  
Dr. Borkan Report at 29.

At page 41 of his expert report, Dr. Borkan states that Fresenius [REDACTED]

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<sup>7</sup>See Memorandum of Decision and Order On the Plaintiffs’ and Fresenius’ Motions Pursuant to *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, and *Commonwealth v. Lanigan*, Doc. 1568-1, filed 12/04/15 at Exhibit 2.

<sup>8</sup>Id.

[illegible][illegible]

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[REDACTED]. Fresenius argued that because Dr. Borkan had not assigned

In addition to the proffered evidence by Dr. Borkan, Dr. Lucius Lampton has submitted

At summary judgment stage, when all factual disputes are viewed in the light most

favorable to non-movant, Plaintiffs have proffered evidence that all Decedents subject to this

motion regarding temporality died within the timeframe referenced by Dr. Borkan and the

Graham Study and summary judgment should be denied. (See Defendants SOF [REDACTED] ¶¶ 67-69;



SOF [REDACTED] ¶ 72; SOF [REDACTED] ¶¶ 79-81; SOF [REDACTED] ¶¶ 87-88; SOF [REDACTED] ¶ 93; SOF [REDACTED] ¶¶ 113-115; SOF [REDACTED] ¶ 119; SOF [REDACTED] ¶¶ 149-151).

**D. The Cause of Death on the Birth Certificates of Each Decedent Are Consistent With Evidence of Plaintiffs' Theory of the Case and Defeat Summary Judgment**

The Immediate Cause of death as identified on each Decedent's Death Certificate, attached hereto as collective Exhibit 4, are as follows:

- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]
- [REDACTED]

Dr. Joseph Akar, a cardiologist designated as an expert for the Plaintiffs, opined in his report that patients with End Stage Renal Disease on hemodialysis are "[REDACTED]

[REDACTED]

[REDACTED]

██” Dr. Akar’s opinions regarding the types of injuries that could be cause by GranuFlo and NaturaLyte create a genuine issue of material fact that precludes summary judgment.

Dr. Julian M. Aroesty, a cardiologist designated as an expert in the case, opines that the

Government	Percentage
Current government	100%
Previous government	0%

The cause of death for each Decedent falls within the category of injury that could have been caused by the use of GranuFlo and NaturaLyte during hemodialysis, according to expert testimony discussed supra. This creates a genuine issue of material fact which precludes summary judgment.

<sup>9</sup>Exhibit 6: Dr. Akar's Expert Report at 15.

<sup>10</sup>Exhibit 7: Aroesty Report at 18.

### **CONCLUSION AS TO GENERAL CAUSATION**

For all of the aforementioned reasons, general causation in this case cannot be credibly contested. The totality and the weight of the evidence, particularly when viewing the evidence in the light most favorable to the non-movant, support causation insofar as the type of injury and the .

#### **E. In the Alternative, Plaintiffs Request Additional Time Pursuant to Rule 56(d)**

In the alternative, Plaintiffs request additional time to respond to the Motion for Summary Judgment On Claims of Opt-Out Cases Lacking Evidence of Elevated Serum Bicarbonate Levels.<sup>11</sup>

### **CONCLUSION**

Repeatedly throughout the course of this litigation, the Fresenius Defendants stood before this Court and argued that the Hakim Memo was unreliable, unsupported, and speculative. Now, in the context of opt-out Plaintiffs whose counsel was not involved in the litigation up until this point, they are asking this Court to grant summary judgment based on that same unreliable, unsupported, and speculative document. This Court should decline to grant that relief. The motion for summary judgment should be denied.

This the 16<sup>th</sup> day of October, 2017.

Respectfully submitted,

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<sup>11</sup>The Affidavit of Dunbar Watt is attached hereto.

s/Dunbar Watt  
Dunbar Watt, Esq.  
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CERTIFICATE OF SERVICE

I hereby certify that on this the 16<sup>th</sup> day of October, 2017, I electronically filed the foregoing with the Clerk of Court by using the CM/ECF system, which will send notice of electronic filing to all counsel of record. I further certify that I mailed the foregoing document and the notice of electronic filing by first-class mail to those who are non-CM/ECF participants.

s/Dunbar Watt  
Dunbar Watt, Esq.  
Attorney for Plaintiffs